UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JEROME DOTTER and SHERYL GREENE-PAYNE, Plaintiffs, v. MERCK & CO., INC. and MERCK SHARP & DOHME CORP., Defendants.	CIVIL ACTION No.: 2:16-cv-04686-HB

ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES, AND JURY TRIAL DEMAND OF DEFENDANTS MERCK & CO., INC. AND MERCK SHARP & DOHME CORP.

Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. (collectively, "Merck"), by and through their undersigned attorneys, hereby answer plaintiffs' Complaint, set forth their affirmative defenses, and demand a trial by jury. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

PARTIES

1. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 1 of the Complaint and therefore denies same.

2. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 2 of the Complaint and therefore denies same.

3. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 3 of the Complaint and therefore denies same.

4. Merck admits that Merck & Co., Inc. is a corporation organized under the laws of the State of New Jersey with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey. Merck denies any remaining allegations contained in Paragraph 4 of

the Complaint.

5. Merck admits that Merck Sharp & Dohme Corp. is a corporation organized under the laws of the State of New Jersey with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey. Merck denies any remaining allegations contained in Paragraph 5 of the Complaint.

6. Paragraph 6 of the Complaint states a characterization of the allegations in the Complaint to which no response is required.

7. Merck admits that it designs, tests, manufactures, labels, licenses, markets, distributes, promotes and sells ZOSTAVAX® in accordance with its FDA-approved prescribing information. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the second sentence of Paragraph 7 of the Complaint and therefore denies same. Merck denies any remaining allegations contained in Paragraph 7 of the Complaint.

8. Merck admits that it maintains a facility within this district called West Point, which is located at 770 Sumneytown Pike, Lansdale, Pennsylvania 19446. Merck further admits that it has manufactured, promoted, marketed, and sold ZOSTAVAX® in this district. Merck denies any remaining allegations contained in Paragraph 8 of the Complaint.

9. Merck admits that it is authorized to conduct business in the State of Pennsylvania. Merck denies any remaining allegations contained in Paragraph 9 of the Complaint.

10. Merck lacks knowledge or information sufficient to form a belief as to what is meant by the phrase "regularly conducted and solicited business" and as to what time period is encompassed by the phrase "at all times relevant hereto," as used in Paragraph 10, and therefore

denies the allegations contained in Paragraph 10 of the Complaint.

11. Merck admits that it does business in Pennsylvania and that it has sold and distributed ZOSTAVAX® in Pennsylvania. Merck denies any remaining allegations contained in Paragraph 11 of the Complaint.

12. Merck lacks knowledge or information sufficient to form a belief as to what is meant by the phrase "derives substantial revenue," as used in Paragraph 12, and therefore denies the allegations contained in Paragraph 12 of the Complaint.

13. Merck admits that, at various times and in accordance with applicable statutory and regulatory requirements, it has advertised ZOSTAVAX® to patients, doctors, and hospitals in Pennsylvania. Merck lacks knowledge or information sufficient to form a belief as to what is meant by the phrase "other medical facilities," as used in Paragraph 13, and therefore denies any remaining allegations contained in Paragraph 13 of the Complaint.

14. Merck admits that, at various times and in accordance with applicable statutory and regulatory requirements, it has advertised ZOSTAVAX® in Pennsylvania. Merck lacks knowledge or information sufficient to form a belief as to what is meant by the phrase "otherwise promotes its business" and therefore denies any remaining allegations contained in Paragraph 14 of the Complaint.

15. The allegations contained in Paragraph 15 of the Complaint state a legal conclusion to which no response is required.

16. The allegations contained in Paragraph 16 of the Complaint state a legal conclusion to which no response is required.

FACTS

17. Merck admits that it designs, manufactures, licenses, labels, tests, distributes,

markets and sells ZOSTAVAX® in accordance with its FDA-approved prescribing information. Merck denies any remaining allegations contained in Paragraph 17 of the Complaint.

18. Merck admits that ZOSTAVAX® was designed, developed, marketed, and sold, in accordance with its FDA-approved prescribing information, with the intended purpose of helping to prevent shingles. Merck further admits that shingles is caused by the reactivation of varicella zoster virus. Merck denies any remaining allegations contained in Paragraph 18 of the Complaint.

19. Merck admits that the varicella zoster virus is a virus that can cause chickenpox. Merck denies any remaining allegations contained in Paragraph 19 of the Complaint.

20. Merck admits that the varicella zoster virus may remain inactive in the nervous system, but denies the implication that it has been proved that the varicella zoster virus remains inactive in the nervous system for many years in all individuals. Merck denies any remaining allegations contained in Paragraph 20 of the Complaint.

21. Merck admits that the varicella zoster virus can be reactivated by certain diseases, stress in certain circumstances, and aging. Merck denies any remaining allegations contained in Paragraph 21 of the Complaint.

22. Merck admits that when reactivated, the varicella zoster virus can replicate in nerve cells and be carried down the nerve fibers to the area of skin served by the ganglion that harbored the dormant virus.

23. Merck admits the allegations contained in Paragraph 23 of the Complaint and respectfully refers the Court to the ZOSTAVAX® May 25, 2006 approval letter for its actual language and full and complete text.

24. Merck admits the allegations contained in Paragraph 24 of the Complaint and

respectfully refers the Court to the ZOSTAVAX® May 25, 2006 approval letter for its actual language and full and complete text.

25. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 25 of the Complaint and therefore denies same.

26. Paragraph 26 of the Complaint contains allegations regarding published literature. That literature speaks for itself. Merck denies any remaining allegations contained in Paragraph 26 of the Complaint, including any allegation that the language set forth in this Paragraph and its respective subparts is a complete statement of the contents of the referenced literature.

27. Merck denies the allegations contained in Paragraph 27 of the Complaint.

28. Merck lacks knowledge or information sufficient to form a belief as to what is meant by the allegations in Paragraph 28 of the Complaint and therefore denies same.

29. Paragraph 29 of the Complaint contains allegations regarding published literature. That literature speaks for itself. Merck denies any remaining allegations of Paragraph 29 of the Complaint, including any allegation that the language set forth in this Paragraph is a complete statement of the contents of the referenced literature.

30. Merck denies the allegations contained in Paragraph 30 of the Complaint.

31. Merck admits that shingles results from a reactivation of latent varicella zoster virus. Merck denies any remaining allegations contained in Paragraph 31 of the Complaint.

32. Merck admits that the May 25, 2006 approval letter from the FDA refers to "postmarketing clinical commitments" for ZOSTAVAX®, and Merck respectfully refers the Court to said approval letter for its actual language and full and complete text.

33. Paragraph 33 of the Complaint contains allegations regarding published literature. That literature speaks for itself. Merck denies any remaining allegations contained in Paragraph

33 of the Complaint, including any allegation that ZOSTAVAX® is not safe and effective when used in accordance with its FDA-approved prescribing information.

34. Merck denies the allegations contained in Paragraph 34 of the Complaint.

35. Merck admits that each 0.5-mL dose of VARIVAX® contains a minimum of 1350 PFU (plaque-forming units) of Oka/Merck varicella zoster virus when reconstituted and stored at room temperature for 30 minutes. Merck further admits that each 0.65-mL dose of ZOSTAVAX® contains a minimum of 19,400 PFU (plaque-forming units) of Oka/Merck strain of varicella zoster virus when reconstituted and stored at room temperature for up to 30 minutes. Merck denies any remaining allegations contained in Paragraph 35 of the Complaint.

36. Merck denies the allegations contained in Paragraph 36 of the Complaint.

37. Merck admits that the FDA-approved prescribing information for VARIVAX® contains a section titled "Adverse Reactions," and Merck respectfully refers the Court to that document for a more complete description of the Adverse Reactions. Merck denies any remaining allegations contained in Paragraph 37 of the Complaint.

38. Paragraph 38 of the Complaint contains allegations regarding the patient information sheet, label, and prescribing information for ZOSTAVAX®. Those documents speak for themselves. Merck denies any remaining allegations contained in Paragraph 38 of the Complaint.

39. Merck admits that ZOSTAVAX® is contraindicated for immunosuppressed or immunodeficient individuals as described in the FDA-approved prescribing information. Merck denies any remaining allegations contained in Paragraph 39 of the Complaint.

40. Paragraph 40 of the Complaint contains allegations regarding the patient information sheet, label, and prescribing information for ZOSTAVAX®. Those documents

speak for themselves. Merck denies any remaining allegations contained in Paragraph 40 of the Complaint, including the allegation that Merck did not adequately address risks associated with ZOSTAVAX®.

41. Paragraph 41 of the Complaint contains allegations regarding the prescribing information for ZOSTAVAX®. That document speaks for itself. Merck denies any remaining allegations contained in Paragraph 41 of the Complaint.

42. Paragraph 42 of the Complaint contains allegations regarding the patient information sheet, label and prescribing information for ZOSTAVAX® and VARIVAX®. Those documents speak for themselves. Merck denies any remaining allegations contained in Paragraph 42 of the Complaint, including the allegation that Merck did not adequately warn of the risks associated with ZOSTAVAX®.

43. Merck denies the allegations contained in Paragraph 43 of the Complaint.

44. Merck admits the allegations contained in Paragraph 44 of the Complaint.

45. Merck denies the allegations contained in Paragraph 45 of the Complaint.

46. Merck denies the allegations contained in Paragraph 46 of the Complaint.

47. Merck lacks knowledge or information sufficient to form a belief as to the truth or the falsity of the allegations contained in Paragraph 47 of the Complaint and therefore denies same.

48. Merck lacks knowledge or information sufficient to form a belief as to the truth or the falsity of the allegations contained in Paragraph 48 of the Complaint and therefore denies same.

49. Merck lacks knowledge or information sufficient to form a belief as to the truth or the falsity of the allegations contained in Paragraph 49 of the Complaint and therefore denies

same.

50. Merck lacks knowledge or information sufficient to form a belief as to the truth or the falsity of the allegations contained in Paragraph 50 of the Complaint and therefore denies same.

51. Merck lacks knowledge or information sufficient to form a belief as to the truth or the falsity of the allegations contained in Paragraph 51 of the Complaint and therefore denies same.

52. Merck lacks knowledge or information sufficient to form a belief as to the truth or the falsity of the allegations contained in Paragraph 52 of the Complaint and therefore denies same.

53. Merck lacks knowledge or information sufficient to form a belief as to the truth or the falsity of the allegations contained in Paragraph 53 of the Complaint and therefore denies same.

54. Merck denies the allegations contained in Paragraph 54 of the Complaint.

55. Merck denies the allegations contained in Paragraph 55 of the Complaint.

56. Merck lacks knowledge or information sufficient to form a belief as to the truth or the falsity of the allegations contained in Paragraph 56 of the Complaint and therefore denies same.

57. Merck denies the allegations contained in Paragraph 57 of the Complaint.

COUNT I
NEGLIGENCE

58. Merck repleads its answers to Paragraphs 1 through and including 57, and by this reference hereby incorporates the same herein in this Paragraph, and makes the same a part hereof as though fully set forth verbatim.

59. The allegations contained in Paragraph 59 of the Complaint state a legal conclusion to which no response is required. To the extent that a response is required, Merck denies these allegations.

60. Merck denies the allegations contained in Paragraph 60 of the Complaint.

61. Merck denies the allegations contained in Paragraph 61 of the Complaint.

62. Merck denies the allegations contained in Paragraph 62 of the Complaint.

63. Merck denies the allegations contained in Paragraph 63 of the Complaint.

64. Merck denies the allegations contained in Paragraph 64 of the Complaint.

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

COUNT II
DESIGN DEFECT

65. Merck repleads its answers to Paragraphs 1 through and including 64, and by this reference hereby incorporates the same herein in this Paragraph, and makes the same a part hereof as though fully set forth verbatim.

66. Merck admits the allegations contained in Paragraph 66 of the Complaint.

67. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 67 of the Complaint and therefore denies same.

68. Merck denies the allegations contained in Paragraph 68 of the Complaint.

69. Merck denies the allegations contained in Paragraph 69 of the Complaint.

70. Merck denies the allegations contained in Paragraph 70 of the Complaint.

71. Merck denies the allegations contained in Paragraph 71 of the Complaint.

72. Merck lacks knowledge or information sufficient to form a belief as to whether

plaintiff and/or plaintiff's healthcare providers used and administered ZOSTAVAX® for its intended purpose and therefore denies same. The allegations contained in the second sentence of Paragraph 72 of the Complaint state a legal conclusion to which no response is required. To the extent a response is required, Merck denies these allegations. Merck denies any remaining allegations contained in Paragraph 72 of the Complaint.

73. Merck denies the allegations contained in Paragraph 73 of the Complaint.

74. Merck denies the allegations contained in Paragraph 74 of the Complaint.

75. Merck denies the allegations contained in Paragraph 75 of the Complaint.

76. Merck denies the allegations contained in Paragraph 76 of the Complaint.

77. Merck denies the allegations contained in Paragraph 77 of the Complaint.

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

COUNT III
FAILURE TO WARN

78. Merck repleads its answers to Paragraphs 1 through and including 77, and by this reference hereby incorporates the same herein in this Paragraph, and makes the same a part hereof as though fully set forth verbatim.

79. Merck admits the allegations contained in Paragraph 79 of the Complaint.

80. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 80 of the Complaint and therefore denies same.

81. Merck denies the allegations contained in Paragraph 81 of the Complaint.

82. The allegations contained in Paragraph 82 of the Complaint state a legal conclusion to which no response is required. To the extent that a response is required, Merck

denies these allegations.

83. Merck denies the allegations contained in Paragraph 83 of the Complaint.

84. Merck denies the allegations contained in Paragraph 84 of the Complaint.

85. Merck denies the allegations contained in Paragraph 85 of the Complaint.

86. Merck denies the allegations contained in Paragraph 86 of the Complaint.

87. Merck denies the allegations contained in Paragraph 87 of the Complaint.

88. Merck denies the allegations contained in Paragraph 88 of the Complaint.

89. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 89 of the Complaint and therefore denies same.

90. The allegations contained in the first clause of the sentence in Paragraph 90 of the Complaint state a legal conclusion to which no response is required. To the extent that a response is required, Merck denies these allegations. Merck denies any remaining allegations contained in Paragraph 90 of the Complaint.

91. Merck denies the allegations contained in Paragraph 91 of the Complaint.

92. Merck denies the allegations contained in Paragraph 92 of the Complaint.

93. Merck denies the allegations contained in Paragraph 93 of the Complaint.

94. Merck denies the allegations contained in Paragraph 94 of the Complaint.

95. Merck denies the allegations contained in Paragraph 95 of the Complaint.

96. Merck denies the allegations contained in Paragraph 96 of the Complaint.

97. Merck denies the allegations contained in Paragraph 97 of the Complaint.

98. Merck denies the allegations contained in Paragraph 98 of the Complaint.

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

COUNT IV
BREACH OF EXPRESS WARRANTY

99. Merck repleads its answers to Paragraphs 1 through and including 98, and by this reference hereby incorporates the same herein in this Paragraph, and makes the same a part hereof as though fully set forth verbatim.

100. Merck denies the allegations contained in Paragraph 100 of the Complaint.

101. Merck denies the allegations contained in Paragraph 101 of the Complaint.

102. Merck denies the allegations contained in Paragraph 102 of the Complaint.

103. Merck denies the allegations contained in Paragraph 103 of the Complaint.

104. Merck denies the allegations contained in Paragraph 104 of the Complaint.

105. Merck denies the allegations contained in Paragraph 105 of the Complaint.

106. Merck denies the allegations contained in Paragraph 106 of the Complaint.

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

COUNT V
BREACH OF IMPLIED WARRANTY

107. Merck repleads its answers to Paragraphs 1 through and including 106, and by this reference hereby incorporates the same herein in this Paragraph, and makes the same a part hereof as though fully set forth verbatim.

108. Merck admits that it manufactures, distributes, advertises, promotes and sells ZOSTAVAX® in accordance with its FDA-approved prescribing information. Merck denies any remaining allegations contained in Paragraph 108 of the Complaint.

109. Merck denies the allegations contained in Paragraph 109 of the Complaint.

110. Merck admits that ZOSTAVAX® is safe and effective for its intended use when used in accordance with its FDA-approved prescribing information. Merck denies any remaining allegations contained in Paragraph 110 of the Complaint.

111. Merck denies the allegations contained in Paragraph 111 of the Complaint.

112. Merck denies the allegations contained in Paragraph 112 of the Complaint.

113. Merck denies the allegations contained in Paragraph 113 of the Complaint.

114. Merck denies the allegations contained in Paragraph 114 of the Complaint.

115. Merck denies the allegations contained in Paragraph 115 of the Complaint.

116. Merck denies the allegations contained in Paragraph 116 of the Complaint.

117. Merck denies the allegations contained in Paragraph 117 of the Complaint.

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

COUNT VI
NEGLIGENT MISREPRESENTATION

118. Merck repleads its answers to Paragraphs 1 through and including 117, and by this reference hereby incorporates the same herein in this Paragraph, and makes the same a part hereof as though fully set forth verbatim.

119. The allegations contained in the first sentence of Paragraph 119 of the Complaint state a legal conclusion to which no response is required. To the extent that a response is required, Merck denies these allegations. Merck denies any remaining allegations contained in Paragraph 119 of the Complaint.

120. Merck admits that ZOSTAVAX® is safe and effective for its intended use when

used in accordance with its FDA-approved prescribing information. Merck denies any remaining allegations contained in Paragraph 120 of the Complaint.

121. Merck denies the allegations contained in Paragraph 121 of the Complaint.

122. Merck denies the allegations contained in Paragraph 122 of the Complaint.

123. Merck denies the allegations contained in Paragraph 123 of the Complaint.

124. Merck denies the allegations contained in Paragraph 124 of the Complaint.

125. Merck denies the allegations contained in Paragraph 125 of the Complaint.

126. Merck denies the allegations contained in Paragraph 126 of the Complaint.

127. Merck denies the allegations contained in Paragraph 127 of the Complaint.

128. Merck denies the allegations contained in Paragraph 128 of the Complaint.

129. Merck denies the allegations contained in Paragraph 129 of the Complaint.

130. Merck denies the allegations contained in Paragraph 130 of the Complaint.

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

COUNT VII
UNJUST ENRICHMENT

131. Merck repleads its answers to Paragraphs 1 through and including 130, and by this reference hereby incorporates the same herein in this Paragraph, and makes the same a part hereof as though fully set forth verbatim.

132. Merck admits that it manufactures, sells, and supplies ZOSTAVAX® in accordance with its FDA-approved prescribing information. Merck denies any remaining allegations contained in Paragraph 132 of the Complaint.

133. Merck lacks knowledge or information sufficient to form a belief as to the truth or

falsity of the allegations contained in Paragraph 133 and therefore denies same.

134. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 134 of the Complaint and therefore denies same.

135. Merck denies the allegations contained in Paragraph 135 of the Complaint.

136. Merck denies the allegations contained in Paragraph 136 of the Complaint.

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

COUNT VIII
LOSS OF CONSORTIUM

137. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 137 and therefore denies same.

138. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 138 and therefore denies same.

139. Merck denies the allegations contained in Paragraph 139 of the Complaint.

140. Merck denies the allegations contained in Paragraph 140 of the Complaint.

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

PRAYER FOR RELIEF

WHEREFORE, Merck respectfully demands judgment dismissing plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as it may deem appropriate. Further, Merck reserves the right to amend its answer to assert additional affirmative defenses as discovery proceeds. Merck demands strict proof of all claims and allegations contained in plaintiffs' Complaint that Merck has not expressly admitted. Further answering and by way of affirmative defense, Merck states as follows:

FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue.

FOURTH AFFIRMATIVE DEFENSE

If plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries, losses, or damages, if any, resulted from the operation of nature, act of God, or other independent, intervening, unforeseeable, or superseding cause or causes.

FIFTH AFFIRMATIVE DEFENSE

To the extent that plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTH AFFIRMATIVE DEFENSE

To the extent that plaintiffs assert claims based upon an alleged failure by Merck to warn plaintiff directly of alleged dangers associated with the use of ZOSTAVAX®, such claims are barred under the learned intermediary doctrine.

SEVENTH AFFIRMATIVE DEFENSE

If plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory or comparative negligence of the allegedly injured plaintiff(s).

EIGHTH AFFIRMATIVE DEFENSE

If plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were sustained only after plaintiff(s) knowingly, voluntarily, and willfully assumed the risk of any such injury or loss.

NINTH AFFIRMATIVE DEFENSE

If plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

TENTH AFFIRMATIVE DEFENSE

If plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries and losses were proximately caused by misuse or abuse of ZOSTAVAX® by plaintiff or his physician.

ELEVENTH AFFIRMATIVE DEFENSE

If plaintiffs have sustained damages, injuries, or losses as alleged in the Complaint, such damages, injuries, or losses, if any, resulted from plaintiff's pre-existing, subsequent, and/or unrelated medical, genetic, or environmental conditions, diseases, or illnesses; idiosyncratic reactions; subsequent medical conditions; or natural courses of conditions for which Merck is not responsible.

TWELFTH AFFIRMATIVE DEFENSE

To the extent that plaintiffs rely upon any theory of breach of warranty, any such claims are barred because plaintiff did not rely on such warranties, Merck did not breach any such warranties, and the claims are otherwise barred for lack of timely notice or lack of privity and/or because the alleged warranties were disclaimed.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because, when the product at issue was designed, manufactured, and distributed, it conformed to the state of the art, it was reasonably safe, and the benefits exceeded any associated risks.

FOURTEENTH AFFIRMATIVE DEFENSE

To the extent that plaintiffs seek punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

FIFTEENTH AFFIRMATIVE DEFENSE

To the extent that plaintiffs seek punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent, and, therefore, any award of punitive damages is barred.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the

Restatement (Second) of Torts.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of ZOSTAVAX® within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under Section 4, *et seq.*, of the *Restatement (Third) of Torts: Products Liability.*

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTIETH AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of ZOSTAVAX®.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part by a failure to mitigate damages.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Merck's conduct conformed with medical knowledge.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to recovery for strict liability because, among other things, comments j and k to Section 402A of the *Restatement (Second) of Torts* relegate plaintiffs' claims to a negligence cause of action.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to recover because if ZOSTAVAX® was unsafe, which Merck denies, then it was unavoidably unsafe as defined in *Restatement of Torts*. The benefits of ZOSTAVAX® exceeded any risk, given the scientific knowledge available when the product was marketed.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the Constitution of the United States of America and the constitution of the State of Pennsylvania.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

The public interest in the benefit and availability of ZOSTAVAX® precludes liability for risks, if any, resulting from any activities undertaken by Merck, which were unavoidable, given the state of human knowledge at the time those activities were undertaken. With respect to plaintiffs' claims, if it is determined that there is a risk inherent in ZOSTAVAX®, then such risk, if any, is outweighed by the benefit of the product.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

At all times relevant herein, ZOSTAVAX® was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA

TWENTY-NINTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part under the applicable state law because ZOSTAVAX® was subject to and received pre-market approval by the FDA.

THIRTIETH AFFIRMATIVE DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-FIRST AFFIRMATIVE DEFENSE

To the extent there were any risks associated with ZOSTAVAX® that Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs have not sustained an ascertainable loss of property or money.

THIRTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs have not suffered any actual injury, loss, or damages.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under the doctrine of economic loss.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' damages, if any, may be barred, limited, or offset in the amount of any reimbursement received by plaintiffs as a result of any insurance or other health benefits plan, or any amounts paid for by any insurance, other health benefits plan, or other collateral sources.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Any liability that might otherwise be imposed upon Merck is subject to reduction by the application of the doctrine of comparative fault.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

To the extent plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to Buckman Co. v. Plaintiff's Legal Committee, 531 U.S. 341 (2001).

THIRTY- EIGHTH AFFIRMATIVE DEFENSE

There is no causal relationship between Merck or its activities described in the Complaint and any injuries or damages allegedly sustained by plaintiffs.

THIRTY-NINTH AFFIRMATIVE DEFENSE

To the extent plaintiffs have settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

FORTIETH AFFIRMATIVE DEFENSE

Merck is not guilty of negligence and violated no duty owing to plaintiffs.

FORTY-FIRST AFFIRMATIVE DEFENSE

The extent of any risk associated with the use of Merck's product, the existence of which is not admitted, was, at the time of the distribution of the product by Merck, unknown and could not have been known by the use of ordinary care by Merck.

FORTY-SECOND AFFIRMATIVE DEFENSE

Each claim asserted or raised in the Complaint is barred by the doctrine of accord and satisfaction, res judicata, payment and/or release.

FORTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' damages are barred or reduced by the doctrine of avoidable consequences.

FORTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred to the extent they have failed to join, in a timely fashion, any and all necessary and indispensable parties.

FORTY-FIFTH AFFIRMATIVE DEFENSE

With respect to plaintiffs' demand for punitive damages, Merck specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions of BMW of North America v. Gore, 517 U.S. 559 (1996), Cooper Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001), State Farm Mut. Auto. Ins. Co. v. Campbell, 538 U.S. 408 (2003), Philip Morris USA v. Williams, 549 U.S. 346 (2007), and Exxon Shipping Co. v. Baker, 128 S. Ct. 2605 (2008).

FORTY-SIXTH AFFIRMATIVE DEFENSE

To the extent that plaintiffs attempt to seek equitable relief, plaintiffs are not entitled to such relief because plaintiffs have an adequate remedy at law.

FORTY-SEVENTH AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver, release, or statutory and regulatory compliance.

FORTY-EIGHTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

FORTY-NINTH AFFIRMATIVE DEFENSE

To the extent that plaintiffs seek punitive damages, such claims are barred because ZOSTAVAX® and its labeling were subject to and received pre-market approval by the FDA.

FIFTIETH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to recover exemplary or punitive damages because exemplary or punitive damages in this case would result in a violation of the due process clause of the Fourteenth Amendment of the United States Constitution and the Pennsylvania Constitution as set forth in State Farm Mutual Automobile Insurance Co. v. Campbell, 123 S. Ct. 1513 (2003).

FIFTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to recover exemplary or punitive damages because exemplary or punitive damages in this case would result in a violation of Merck's constitutional protection and the prohibitions against double jeopardy set forth in the Fifth Amendment and the due process clause of the Fourteenth Amendment of the United States Constitution and comparable provisions of the Pennsylvania Constitution.

FIFTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to recover exemplary or punitive damages because exemplary or punitive damages in this case would result in an unconstitutionally excessive fine in violation of the Eighth Amendment and the Due Process Clause of the Fourteenth Amendment of the United States Constitution and comparable provisions of the Pennsylvania Constitution.

FIFTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to recover exemplary or punitive damages because exemplary or punitive damages in this case would result in a violation of the prohibition against ex post facto laws and laws impairing the obligations of contracts contained in Sections 9 and 10 of Article I of the United States Constitution and comparable provisions of the Pennsylvania Constitution.

FIFTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to recover exemplary or punitive damages because plaintiffs' claim for exemplary or punitive damages, if any, is in violation of the due process clauses of the Fifth and Fourteenth Amendments to the United States Constitution and comparable provisions of the Pennsylvania Constitution because there are not realistic standards or limits imposed on the amount of punitive damages which may be awarded, and no required relationship between the actual damages sustained and the amount of punitive damages which may be awarded.

FIFTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to recover exemplary or punitive damages because plaintiffs' claim for exemplary or punitive damages, if any, is in violation of the due process clauses of the Fifth and Fourteenth Amendments to the United States Constitution and comparable provisions of the Pennsylvania Constitution because the vague standards employed in punitive damage cases result in extremely disparate results among similar defendants accused of similar conduct.

FIFTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to recover exemplary or punitive damages because plaintiffs' claim for exemplary or punitive damages, if any, is in violation of the due process clauses of the Fifth and Fourteenth Amendments to the United States Constitution and comparable provisions of the Pennsylvania Constitution because the purpose of punitive damages is punishment and deterrence, and there are not adequate procedural safeguards in place to protect Merck's right against self-incrimination, right to proof beyond a reasonable doubt, and right to be free from unreasonable searches and seizures in this case.

FIFTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to recover exemplary or punitive damages because plaintiffs' claim for exemplary or punitive damages, if any, is in violation of the First Amendment to the United States Constitution and comparable provisions of the Pennsylvania Constitution.

FIFTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to recover exemplary or punitive damages because the standards and instructions regarding exemplary/punitive damages are inadequate, vague, and ambiguous, further violating the Due Process Clause of the Fourteenth Amendment of the United States Constitution and the Pennsylvania Constitution.

FIFTY-NINTH AFFIRMATIVE DEFENSE

The correct standard for submitting the burden of proof for exemplary and/or punitive damages is "clear and convincing" evidence. Any lesser standard is a violation of the Due Process Clause of the Fourteenth Amendment of the United States Constitution and the Pennsylvania Constitution.

SIXTIETH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to recover exemplary or punitive damages because the imposition of exemplary or punitive damages in this case, based upon evidence of Merck's wealth or financial status, would violate the due process clauses of the Fifth and Fourteenth Amendments to the United States Constitution and comparable provisions of the Pennsylvania Constitution.

SIXTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims based on inadequate warning, if any, are barred even if Merck allegedly failed to provide adequate warnings with respect to ZOSTAVAX® because physicians prescribing the product either knew or should have known of the potential or known dangers or risks, and there is no duty to warn members of a profession against dangers known or which should be known to members of the profession.

SIXTY-SECOND AFFIRMATIVE DEFENSE

Merck's products and/or actions were not the cause in fact, not the proximate cause, and/or not the producing cause of plaintiffs' alleged damages, injuries, or losses.

SIXTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries, losses, or damages were not caused by any product manufactured, distributed, or sold by Merck, but rather by some other product, process, occurrence, event, or service over which Merck exercised no control or right of control.

SIXTY-FOURTH AFFIRMATIVE DEFENSE

If Plaintiffs have sustained damages, injuries, or losses as alleged in the Complaint, such damages, injuries, or losses, if any, resulted from the actions of persons or entities for which Merck is not responsible.

SIXTY-FIFTH AFFIRMATIVE DEFENSE

The product at issue was not defectively manufactured, was not defectively designed, and was reasonably fit, suitable, and safe for its intended purpose.

SIXTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims may be barred, in whole or in part, by the doctrine of informed consent.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual, and equitable rights, Merck reserves the right to amend and/or supplement the averments of its answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing the Complaint with prejudice and awarding Merck its reasonable costs and disbursements, including reasonable attorneys' fees as may be available by law, together with such and other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury of twelve (12) persons as to all issues so triable.

Dated: December 16, 2016

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